IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
ASHEVILLE DIVISION
CIVIL CASE NO. 1:22-cv-00141-MR

BARBARA A. BEAVER,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**MEMORANDUM OF**
	)	**DECISION AND ORDER**
	)	
PFIZER INC.,	)	
	)	
Defendant.	)	
	)	

THIS MATTER is before the Court on the Defendant's Motion to Dismiss [Doc. 5] and the Plaintiff's Petition for Exemption to Pay Fees for PACER [Doc. 14].

I. PROCEDURAL BACKGROUND

The Plaintiff, Barbara A. Beaver ("Plaintiff"), appearing *pro se*, filed a Complaint in North Carolina state court on June 14, 2022, against Defendant Pfizer Inc. ("Defendant"). [Doc. 1-1]. The Complaint asserts a single cause of action for negligence. [Id.]. On July 21, 2022, the Defendant filed a notice of removal to federal court, alleging diversity jurisdiction pursuant to 28 U.S.C. § 1332 as the Plaintiff is a citizen of North Carolina and the Defendant is a corporation with citizenship in Delaware and New York and the Plaintiff alleges damages in excess of $75,000. [Doc. 1].

On July 28, 2022, the Defendant filed a Motion to Dismiss for Failure to State a Claim pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. [Doc. 5]. On August 9, 2022, the Plaintiff filed a Response in Opposition to the Defendant's Motion to Dismiss. [Doc. 11]. On August 16, 2022, the Defendant filed a Reply to the Plaintiff's Response. [Doc. 12]. On February 16, 2023, the Plaintiff filed a Petition for Exemption to Pay Fees for PACER. [Doc. 14]. Thus, the matter has been fully briefed and is ripe for disposition.

II. STANDARD OF REVIEW

The central issue for resolving a Rule 12(b)(6) motion is whether the claims state a plausible claim for relief. See Francis v. Giacomelli, 588 F.3d 186, 189 (4th Cir. 2009). In considering the Defendant's motion, the Court accepts the allegations in the Complaint as true and construes them in the light most favorable to the Plaintiff. Nemet Chevrolet, Ltd. V. Consumeraffairs.com, Inc., 591 F. 3d 250, 253 (4th Cir. 2009); Giacomelli, 588 F.3d at 190-92.

When considering a motion to dismiss, the Court is obligated to construe a *pro se* complaint liberally, "however inartfully pleaded[.]" Booker v. S.C. Dep't of Corrs., 855 F.3d 533, 540 (4th Cir. 2017) (quoting Erickson v. Pardus, 551 U.S. 89, 94 (2007)). Although the Court accepts well-pled

facts as true, it is not required to accept "legal conclusions, elements of a cause of action, and bare assertions devoid of further factual enhancement." Consumeraffairs.com, 591 F.3d at 255; see also Giacomelli, 588 F.3d at 189.

The claims need not contain "detailed factual allegations," but must contain sufficient factual allegations to suggest the required elements of a cause of action. Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007); see also Consumeraffairs.com, 591 F.3d at 256. "[A] formulaic recitation of the elements of a cause of action will not do." Twombly, 550 U.S. at 555. Nor will mere labels and legal conclusions suffice. Id. Rule 8 of the Federal Rules of Civil Procedure "demands more than an unadorned, the defendant-unlawfully-harmed-me accusation." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

The Complaint is required to contain "enough facts to state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 570; see also Consumeraffairs.com, 591 F.3d at 255. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678; see also Consumeraffairs.com, 591 F.3d at 255. The mere possibility that a defendant acted unlawfully is not sufficient

for a claim to survive a motion to dismiss. Consumeraffairs.com, 591 F.3d at 256; Giacomelli, 588 F.3d at 193. Ultimately, the well-pled factual allegations must move a plaintiff's claim from possible to plausible. Twombly, 550 U.S. at 570; Consumeraffairs.com, 591 F.3d at 256.

III. FACTUAL BACKGROUND

Construing the well-pled factual allegations of the Complaint as true and drawing all reasonable inferences in the Plaintiff's favor, the following is a summary of the relevant facts.

In 2005, the Plaintiff was prescribed Celebrex, a prescription medication manufactured by the Defendant, as a treatment for arthritis. [Doc. 1-1 at ¶ 1]. In 2020, the Plaintiff was diagnosed with Stage 3 chronic kidney disease. [Id. at ¶ 5]. The Plaintiff attributes this kidney disease to Celebrex. [Id. at ¶ 8]. She reached this conclusion because her doctor recommended that she stop taking Celebrex due to her kidney disease and because her kidney function gradually increased after she stopped taking Celebrex. [Id. at ¶¶ 6-8]. The Plaintiff also alleged that she did not have any other medication, health, or lifestyle changes to which the improved kidney function could be attributed. [Id. at ¶ 9]. As a result of her diminished kidney function, the Plaintiff cannot take anti-inflammatories or arthritis medication and is therefore left in "constant pain." [Id. at ¶ 10].

The Plaintiff alleges that in 2005, the United States Food and Drug Administration ("FDA") "suggested" that the Defendant remove Celebrex from the market due to heart and stroke complications. [Id. at ¶ 2]. The Defendant did not remove Celebrex from the market but did add a warning label regarding potential heart and stroke complications. [Id.]. Celebrex's label does not, however, contain a warning about potential kidney damage. [Id.].

IV. DISCUSSION

A. Motion to Dismiss

The Plaintiff asserts a claim for negligence, arguing that the Defendant breached a duty to remove Celebrex from the market, or, in the alternative, breached a duty to include potential kidney damage on Celebrex's warning label.

1. Failure to Remove Celebrex from the Market

The Plaintiff alleges that "[i]f Defendant had taken Celebrex off the market as suggested by the FDA in 2005, Plaintiff would not have permanent kidney damage and would still be able to take anti-inflammatory medications for her arthritis." [Doc. 1-1 at ¶ 16]. The Plaintiff also alleges that "Defendant knew or should have known that Celebrex would cause permanent kidney damage." [Id. at ¶ 17]. The Defendant, on the other hand, argues that any

state-law duty to remove Celebrex from the market is preempted by federal law, specifically the Food, Drug, and Cosmetic Act ("FDCA"). [Doc. 6 at 3].

The Supremacy Clause of the Constitution makes evident that "state laws that conflict with federal law are 'without effect.'" Altria Grp., Inc. v. Good, 555 U.S. 70, 76 (2008) (quoting Maryland v. Louisiana, 451 U.S. 725 (1981)). A state law can be preempted via: (1) express preemption, (2) field preemption, or (3) conflict preemption. Id. at 76-77. Conflict preemption, the only type of preemption relevant here, exists where "there is an actual conflict between state and federal law," id., and the "state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" Hillsborough Cnty. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985) (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)). In other words, a state law is preempted "where it is 'impossible for a private party to comply with both state and federal requirements.'" Mutual Pharmaceutical Co., Inc. v. Bartlett, 570 U.S. 472, 480 (2013) (quoting English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990)).

In Bartlett, the Supreme Court considered whether a pharmaceutical company's state-law duty to strengthen a generic drug's label was preempted by the FDCA's prohibition on changes to generic drug labels. Id. at 479-80. The Court held that the FDCA preempted the state law because

it was impossible to comply with both the state-law duty and the federal law. Id. at 480. In reaching its conclusion, the Court specifically rejected the theory that conflict preemption could be avoided because pharmaceutical company could comply with seemingly irreconcilable state and federal laws by ceasing production of the drug altogether. Id. at 488. The Court stated that "[o]ur pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." Id.

Here, the Defendant argues, any state-law duty to withdraw Celebrex from the market is preempted because the only way to comply would be to "ceas[e] production of the drug altogether," the precise theory of compliance rejected by the Court in Bartlett. [Doc. 6 at 6]. Here, Celebrex was and continues to be an FDA-approved medication and allowing a state-law duty to nonetheless prohibit sale would frustrate the purposes of the FDA's regulatory scheme. See Gross v. Pfizer, Inc., 825 F. Supp. 2d 654, 659 (D. Md. 2011) ("The Court is aware of no state law duty that would compel generic manufacturers to stop production of a drug that under federal law they have the authority to produce. Nor could such a state law duty exist, as it would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug may be

marketed in interstate commerce.") The Court therefore concludes that the Plaintiff's theory of breach is the precise "stop-selling" rationale explicitly rejected by the Supreme Court and, accordingly, the Plaintiff has failed to state a claim of negligence based on this theory.

2. Failure to Warn

The Plaintiff also alleges that, because "Defendant knew or should have known that Celebrex would cause permanent kidney damage," it should have "add[ed] the warning of same for patients [sic] knowledge." [Doc. 1-1 at ¶ 17]. The Court construes this statement as asserting a cause of action for failure to warn. "In North Carolina, a failure to warn claim requires the plaintiff to prove that the defendant unreasonably failed to provide an adequate warning, such failure was the proximate cause of the plaintiff's damages, and the product 'posed a substantial risk of harm' without an adequate warning either at the time of or after leaving the manufacturer's control." Carlson v. Boston Scientific Corp., 856 F.3d 320, 324 (4th Cir. 2017) (quoting N.C. Gen. Stat. § 99B-5(a)). At the outset, the Complaint does not include allegations that the failure to provide a warning of kidney damage was unreasonable or that such failure was the proximate cause of her injuries. The allegations related to failure to warn are essentially a formulaic

recitation of the third element of the failure to warn test under North Carolina law, which is inadequate to state a claim. See Twombly, 550 U.S. at 555.

Moreover, under North Carolina law: "[N]o manufacturer or seller of a prescription drug shall be liable in a products liability action for failing to provide a warning or instruction directly to a consumer if an adequate warning or instruction has been provided to the physician or other legally authorized person who prescribes or dispenses that prescription drug for the claimant unless the United States Food and Drug Administration requires such direct consumer warning or instruction to accompany the product." N.C. Gen. Stat. § 99B-5(c). The Plaintiff does not allege that the FDA requires a direct consumer warning and does not allege that the warning or instruction provided to her physician was inadequate. Nor does she allege that her physician would not have prescribed Celebrex, or that she would not have taken Celebrex, if a warning of kidney damage was included on the label.

As the Plaintiff has failed to allege facts that would state a claim for failure to warn under North Carolina law, and as her other theory of breach is preempted by federal law, the Court concludes that she has not stated a claim for negligence. Accordingly, the Court will dismiss the Complaint with prejudice.

B. Petition for Exemption from PACER Fees

The Plaintiff filed a petition requesting that the Court exempt her from PACER fees during the duration of this case. [Doc. 14]. As the Court is dismissing the action, the Plaintiff's petition will be denied as moot.

IT IS, THEREFORE, ORDERED that the Defendants' Motion to Dismiss [Doc. 5] is **GRANTED.**

IT IS FURTHER ORDERED that the Plaintiff's Petition for Exemption to Pay Fees for PACER is **DENIED AS MOOT.**

IT IS SO ORDERED.

Signed: March 6, 2023

Martin Reidinger
Chief United States District Judge